



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
WATER

SUBJECT: April 26, 1996 Meeting with Inter-industry Analytical Group

FROM: William A. Telliard, Director
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TO: Tudor T. Davies, Director
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On April 26, representatives from OST and OWM met with representatives from the Inter-industry Analytical Group (IIAG) to discuss detection and quantitation limits. IIAG is a consortium of trade associations and companies in the regulated community that focuses primarily on the impact of analytical chemistry issues on various EPA regulations. The meeting was held to address IIAG's September 22, 1995 request for a meeting to further discuss their proposed alternate minimum level (AML). That request was submitted following the August 2-3, 1995, public meeting on water quality-based effluent limits (WQBELs) set below the analytical detection limit held in McLean, VA. A complete list of participants at the April 26 meeting is provided as Attachment 1 to this memo.

In order to ensure that the meeting was as productive as possible, the meeting focused on EPA's technical concerns with the AML. Prior to the meeting, OST and OWM forwarded a list of 12 concerns (Attachment 2). At the meeting, IIAG presented a response to each concern. IIAG also will present their responses to these issues at the upcoming Annual Conference on the Analysis of Pollutants in the Environment, to be held on May 14-16 in Norfolk, VA. Following IIAG's presentation of their rebuttal to EPA's concerns, EPA presented preliminary results from a recent study of detection and quantitation limits, including the AML, the minimum level (ML), and the method detection limit (MDL). These results also will be presented at the Norfolk Conference, and we have agreed to provide IIAG with copies of the data that support these results as soon as these data have undergone a thorough review.

A productive exchange was held during the meeting, with IIAG acknowledging that the AML was still under development and would need further refinement before it could be adopted, and with EPA acknowledging that additional guidance regarding MDL/ML procedures is needed in the WQBEL guidance to address some of the concerns raised by IIAG. Based on the information presented by IIAG at the April 26 meeting, we still are not convinced that the AML offers a significant advantage over the ML approach currently being followed within OW. We believe that problems with the AML can be generally categorized within one of two specific issues.

First, the AML is not appropriate for use as compliance evaluation threshold when the WQBEL is below the analytical limit of detection. In such circumstances, a more appropriate level is a detection level analogous to the MDL. Such levels are typically below the AML, the ML, or any other quantitation level. OW's current approach of setting compliance evaluation thresholds at the ML



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instead of the MDL reflects a policy decision aimed at providing some concession to permittees concerned about the reasonableness of enforcing compliance limits at the analytical detection limit.

The second major problem with the AML is that, even when removed from the context of regulating WQBELs below the detection limit, the AML presents serious regulatory obstacles when used as a quantitation limit. This is because the AML requires a measurement certainty based on 10 percent relative standard deviation (RSD). For many pollutants currently regulated under the Clean Water Act and Safe Drinking Water Act, measurement limitations preclude achievement of 10 percent RSD. Therefore, adoption of the AML could be a serious impediment to the regulation of compounds for which this criterion cannot be achieved. The principle behind the ML approach advocated by OW is based on the 10 percent RSD concept, but use of a simple multiplier to establish the ML allows any pollutant to be measured, regardless of the measurement error.

It is important to note that issues concerning the MDL and ML have been raised almost exclusively by the regulated community. Analytical laboratories responsible for making measurements at these levels have not expressed much interest in alternate quantitation limit concepts such as the AML. We believe that once the full procedure for establishing an AML is understood by analysts, nearly all analysts will reject the AML because of its complexity and the fact that the level produced is almost identical to the ML.

Near the end of the meeting with IIAG, we agreed to gather additional data for further evaluation of the ML and AML concepts. Data that we presented at the meeting, and which will be amplified at the upcoming conference in Norfolk, are the only data collected by EPA, industry, or any other party that allows a fair comparison of various detection and quantitation limit concepts, including the ML and AML. Additional data are needed because EAD's study focused exclusively on data gathered from a single instrument using a single method. We believe that further data gathering will only support the position that the ML is a reasonable quantitation limit.

In a meeting with OWM (Jim Taft and Irene Dooley) after the meeting with IIAG, we mutually agreed that EPA's draft "National Guidance for the Permitting, Monitoring, and Enforcement of Water Quality-based Effluent Limitations Set Below Analytical Detection/Quantitation Levels" (WQBEL Guidance) would retain the ML as the quantitation limit to be used as the compliance evaluation threshold, but would be revised to allow other approaches of establishing the quantitation limit (such as the AML), provided that the other limit is as protective of the environment as the ML. The WQBEL Guidance would retain the policy that the ML or alternate limit would be used to evaluate compliance when the WQBEL is below the analytical limit of detection.

If you would like to further discuss this meeting or our continued concerns about the AML as a quantitation limit or as a compliance evaluation threshold, please call me when convenient.

Attachments

cc: S. Frace
J. Taft
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Attachment 1
List of Participants

EPA and Inter-industry Analytical Group Meeting

-- Participant List --

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Attachment 2

List of EPA Concerns with the AML

AML Issues for Discussion

1. There is no evidence to date that the AML provides a better estimate of the quantitation level than the ML. In fact, there may be some evidence that measurements at or near the detection/quantitation limit provide the best estimate of these limits. Results to date indicate that data collected in the region of proportional error are not relevant to construction of detection and quantitation limits. Therefore, there is a heavy burden on proponents of concepts that use such data to demonstrate relevance, not through theoretical discussions, but with analytical chemical data.
2. The AML is too complex. The required statistical sophistication will reduce the utility of the AML because the AML will not be understood by the bench chemist. Use of the AML by unsophisticated users will result in unpredictable results.
3. Software for establishing the AML is "black box," resulting in largely uncontrolled results except in the hands of a skilled user.
4. Calculation of the AML involves fitting the curve of precision vs spike concentration, including both the selection of the form of the curve and fitting the curve to the data. To minimize costs, and in the absence of interlaboratory data, the AML proponents suggest using single-laboratory data with an interlaboratory multiplier. In this construction, the amount of data proposed (triplicate determinations at four levels) is marginal at best for distinguishing between competing mathematical curve forms, yet the choice of curve form can have a significant effect on the resultant AML. There is not enough data to show whether one curve form can be selected as being both robust and flexible enough to be adopted as the standard form, yet the proponents of the AML leave selection of the curve form at the discretion of the user, a highly undesirable situation.
5. It is unclear whether the statistical fitting process for the precision curve has been addressed sufficiently. Issues of what weights are appropriate and the non-normality of standard deviation/variance data, even when the concentration data are normally distributed, are not addressed in any of the discussions provided by the proponents.
6. One criticism of the MDL has been that it is sensitive to the spiking level. However, preliminary results from bootstrap simulations using metals data show the AML to have at least as much variability as the ML, particularly when using the design with three measurements at each of four concentrations. The selection of the four levels also introduces variability. If these levels are chosen inappropriately, not only can high AMLs, low AMLs, and AMLs equal to zero be produced, but negative AMLs also can be produced.
7. Other than the study of trace metals by ICP/MS conducted by EPA's Engineering and Analysis Division (EAD), the Office of Water is unaware of any study that provides a database that allows a direct, fair comparison of the ML, AML, LOQ, and other quantitation limit concepts. In the absence of fair comparative data that demonstrate a clear and recognizable advantage to the AML or any other concept, EPA cannot justify changing to an alternate concept.
8. The AML has been advanced as the compliance evaluation threshold (CET) to be used when the water quality-based effluent level (WQBEL) is below the analytical limit of detection. The AML concept allows for false negatives and sets the CET at 10 sigma. EPA has received

persuasive arguments that allowance for false negatives and a 10 sigma multiplier are unnecessary for setting the CET. If EPA accepts these arguments, the need for the AML (and the ML) are eliminated in favor of a detection or critical level as the CET.

9. The large number of laboratories suggested for an interlaboratory study (30) will preclude use of the AML. The use of an interlaboratory multiplier solves this problem, but an interlaboratory multiplier also can be used with the ML. Therefore, the issue is not the AML, ML, or any other quantitation limit concept, but **whether** an estimate of interlaboratory variability should be allowed with any of these **concepts**.
10. The AML is the concept of these times. The last concepts advanced by many of the proponents of the AML were the compliance monitoring detection level (CMDL) and compliance monitoring quantitation level (CMQL). IUPAC has now revised detection and quantitation level concepts. In 1994, the American Chemical Society attempted to advance the concepts of the reliable detection level (RDL) and reliable quantitation level (RQL). A 99 percent/95 percent interlaboratory detection estimate (99/95 IDE) has been proposed within the ASTM D-19 Committee. In an article in January 1995, the Water Environment Federation supported the practical quantitation level (PQL). EPA cannot change detection/ quantitation level concepts based on the latest desires of a single organization or group of organizations. If EPA is to change concepts, a more logical change would be to a concept advanced by a consensus organization such as IUPAC, ISO, ACS, or ASTM. EPA believes that the MDL/ML remains consistent with the concepts in use by nearly all of these organizations.
11. The present embodiment of the AML does not require pre-qualification of laboratories, possibly resulting in an inflated AML resulting from poorly performing laboratories. Having laboratories demonstrate that a given detection level can be achieved is a means of assuring that measurements at that detection level can be made.
12. EPA may be better served, in terms of (1) reduced effort, (2) a more user-friendly product, and (3) statistical correctness, by upgrading the MDL to correct the statistical error in documentation of the MDL at 40 *CFR* 136 and by providing more guidance for use of the MDL. Correcting the statistical error requires dividing the product of the t-statistic and the standard deviation by the square root of n, the number of measurements used to estimate the standard deviation. It should be noted that the resultant detection level would be reduced in magnitude from the existing MDL.